K935732

510(k) Summary

2. Summary and Certification.

2.1. Safety and efficacy of exercise testing in general.

2.1.1. Safety of the exercise test.

Rochmis and Blackburn reported a survey of the safety experience of 170000 exercise stress tests performed in 73 medical centers [9]. Sixteen documented deaths were attributed to the exercise, a mortality of less than 1 in 10000. Nonfatal complications that required hospitalization within 1 week after the test occurred at the rate of about 3 per 10000. A more recent survey reported 17 deaths among 712285 patients tested (1 in 40000) [6], with nonfatal ventricular fibrillation occurring at a rate of one per 7000 tests, and nonfatal myocardial infarction at a rate of one per 70000 tests.

In a report of 1377 symptom-limited exercise tests performed in 263 patients with histories of ventricular tachycardia or fibrillation, serious but nonfatal arrhythmia complications occurred during 2.3% of the tests, involving 9.1% of the patients [12]. The incidence of such complications in 8221 maximal exercise tests involving 3444 patients without histories of sustained ventricular arrhythmias performed in the same institution was 0.05%.

2.1.2. Efficacy of the exercise test.

Sensitivity and specificity of exercise testing are dependent on a number of variables. Among these are the lead system employed, the (ST) criteria used, and the incidence of CAD in the test population. In a study reported by McNeer and associates in 1978 [8] of 1472 patients, the sensitivity was 57% and the specificity 90%. Deckers [3] reports a sensitivity and specificity, respectively, of 77% and 90% in females and 74% and 90% in males, in 1988 at the Thorax Centrum in Rotterdam, the Netherlands. Simoons at the same institute attributes reports of high incidence of both false positives and false negatives in subgroups of patients largely on patient selection.

Both coronary arteriography with angiographic evaluation of left ventricular function and exercise testing can provide prognostic information in patients with CAD [2]. Gohlke et al. [5] analyzed the additional prognostic value of exercise testing in 1034 patients with known CAD and normal or mildly impaired left ventricular function. In various subgroups, five-year survival was highest in patients with a better exercise tolerance. For example, in patients with double-vessel disease, five-year survival was 95±2% in those with exercise tolerance greater than 110W and only 81±5% in those who performed less than 90W.

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2.2. Safety and efficacy of Cardio Perfect ST.

Unit testing.

A total of about 10 Cardio Perfect MD units were tested for compliance with all system specifications. Some of these were tested in-house as part of the design verification and testing phases of development, and some at institutions like the German TÜV for testing of compliance to local and international standards like the IEC-601.
In the volume production, tests are performed to verify correct operation of each produced device.

Recorder testing

After confirming that the optical transmission section of the recorder operates properly, the devices are burnt in for 24 hours. After that, the lead connections, gain, time base etc. are measured by recording an ECG with a simulator. Measurements of these recordings are stored and compared, and the ECG is superimposed on a reference ECG on a color monitor for visual inspection.
Before the unit is sent to the client (which may be after a time of storage), four more ECGs are recorded with standard simulator settings, and compared against reference recordings.
Parameters like defibrillation overload recovery and gain drift are met by design and are not tested for each produced device.
About 450 Cardio Perfect recorders have been produced to date.

CPCOM testing

The first CPCOM tests are performed after production at the same time as testing of the recorders. This is a simple check of proper operation which lasts between one and two minutes (not exhaustive), by recording a resting ECG.

The CPCOM cards are then tested by inserting them into a PC on which special test software is running. A small device generates a pattern of bytes which are sent through the same optical connection as is utilized with the Cardio Perfect recorder. Only, the pattern is known (actually a simple counter), so the software can check every bit of incoming information. With a standard recorder, only 5 bits in every 2-byte sample are predictable. Also, the baudrate used for testing is the maximum baudrate (460800) which the CPCOM can accommodate, which is eight times faster than needed for a standard Cardio Perfect recorder.

Through a DMA channel on the card, the testing software (a TSR) can monitor two cards in one PC at the same time while allowing the PC to be used for other purposes as well. When errors are encountered, a window pops up to report this fact. The cards are tested in this fashion over a period of at least an hour, usually longer.

To date, one CPCOM card was returned which was reported defective, but the jumper settings turned out not to match the settings the client entered in the program.

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